

REMARKS

Claims 1-31 are pending in the present application.

The rejection of Claims 2, 3, 7, and 8 under 35 U.S.C. §112, first paragraph, is traversed.

The Examiner has rejected these claims for lack of enablement of the scope of "cell incorporated type three-dimensionally reconstructed tissue." Applicants submit that this rejection is unfounded and should be withdrawn.

Due to recent developments in tissue engineering technology, various cells derived from animals can form the cell incorporated type three-dimensional reconstructed tissue. Applicants submit herewith U.S. Patent No. 5,985,539, which is a member of the patent family of Japanese Patent Application Laid-Open No. 11-164684 disclosed on page 3, line 12 and page 14, line 20 to page 15, line 5 of the specification as originally filed. In U.S. Patent No. 5,985,539, Applicants describe a novel organ engineering method of reconstructing an organ-like construct (an organoid) by subjecting continuous three-step perfusion on an organ to remodel the organ into a culture version organoid without separating the majority of constructive cells in the objective organ. In particular, U.S. Patent No. 5,985,539 provides various tissues or organs and methods that may be used to produce cell incorporated type three-dimensional reconstructed tissues.

Therefore, it would be well within the purview of the skilled artisan to practice the present invention as claimed while having the present specification in hand, along with U.S. Patent No. 5,985,539.

The Examiner has held that the specification does not provides support for a carrier that contains an extracellular matrix or the use of any natural or synthetic thread in the mesh

network that is bioabsorptive. However, Applicants submit that with the present specification in hand the skilled artisan would be fully enabled to make and use the present invention in its entirety. At page 3, lines 5-6, page 14, line 20 to page 15, line 5, and page 15, line 20 to page 16, line 5 of the specification as originally filed, Applicants refer the artisan to Japanese Patent Application Laid-open No. Hei 7-298876 (corresponding to U.S. Patent No. 5,736,399, submitted herewith) and Japanese Patent No. 3081130. In these disclosures, Applicants provide the basic technology of tissue engineering with utilizing a mesh network such as cotton gauze as a support. In addition, these references also provide various extracellular matrix components and mesh bodies, which can be contained in the cell incorporated type three-dimensional reconstructed tissue.

Moreover, at page 11, line 17 to page 12, line 5 of the specification as originally filed, Applicants explicitly describe suitable extracellular matrices, which may include collagen, fibronectin, vitronectin, laminin, proteoglycan, and glycosaminoglycan. In addition, at page 12, line 6 to page 13, line 18 of the specification as originally filed, Applicants provide a detailed summary of acceptable mesh networks, as well as providing a list of suitable synthetic threads that may be used to form the mesh networks in accordance with the present invention.

The Examiner's argument seems to center on the lack of working examples that exemplify the entire range of the claims. However, Applicants submit that MPEP §2164.02 states:

The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation.

For the reasons set forth above, Applicants submit that the specification adequately provides the artisan with sufficient direction so as to enable one to practice the invention without an undue amount of experimentation. Accordingly, when the present specification is

considered in its entirety, including the disclosures of the references cited therein, the skilled artisan would be able to practice the claimed invention requiring nothing more than routine skill.

In view of the foregoing, Applicants respectfully request withdrawal of this ground of rejection

The rejection of Claims 1-3, 7, and 8 under 35 U.S.C. §112, second paragraph, is obviated in part by amendment and traversed in part.

The Examiner holds the phrase "cell incorporated type three-dimensionally reconstructed tissue" to be a "broad, undefined term for which no description in the specification is provided" (paper number 3, page 2, lines 16-18). However, Applicants submit that this assertion is without merit. Applicants refer the Examiner to page 9, lines 19-21 of the specification as originally filed, which states: "Herein, the cell incorporated type three-dimensionally reconstructed tissue is one to become a scaffold for growing a three-dimensional tissue derived from the fertilized ovum." Therefore, based on the description provided in the present specification, it is clear that the cell incorporated type three-dimensionally reconstructed tissue is a scaffold for cellular growth thus substituting for the natural function of the endometrium, i.e., supporting growth of a fertilized egg once it is implanted. Applicants submit that this phrase is clearly defined in the specification, and as such is definite within the meaning of 35 U.S.C. §112, second paragraph.

With regards to the term "co-culturing," Applicants submit that a fertilized ovum is co-cultured with a carrier of the present invention, and "cells" are incorporated into the carrier comprising cell incorporated type three-dimensionally reconstructed tissue (see Claim 1). Therefore, a fertilized ovum is co-cultured with the cells incorporated into the carrier. The

meaning of this term is more clearly defined by amended Claim 1, and would be readily understood by the skilled artisan.

Applicants respectfully request withdrawal of this ground of rejection.

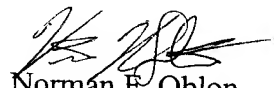
The objection to Claims 4, 5, 6, 9, and 10 under 37 C.F.R. §1.75(c) is obviated by amendment. All multiple dependencies have been removed.

In addition, the objection to the specification is believed to be obviated by submission of the attached substitute specification. Applicants submit that the substitute specification contains no new matter.

Applicants submit that the present application is now in condition for allowance. Early notification of such action is earnestly solicited.

Respectfully submitted,

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IN THE SPECIFICATION

Please amend the paragraph beginning at page 1, line 12 as follows:

According to the present invention, the fertilized ovum of an animal can be grown three-dimensionally in a culture system[, and thus]. As such, the present invention is useful for elucidation of the differences between the three-dimensional growth of the fertilized ovum in an in vitro culture system and the development of the early embryo from the fertilized ovum implanted in vivo[.]. In addition, the present invention is useful for the evaluation of teratogenic materials, or grafting of an embryo initially developed from the fertilized ovum[, etc].

Please amend the paragraph beginning at page 1, line 21 as follows:

Hitherto, [there has been established] an assisted reproductive technology (ART) has been established, not only in a veterinary field but also in a human sterility treatment [, wherein]. In this ART a spermatozoon and an ovum are fertilized in vitro in a culture system to prepare a fertilized ovum (a zygote). Then the fertilized ovum can be cultured via cleavage, morula and blastocyst stages to a hatching-blastocyst stage, a late blastula stage wherein azona pellucida is denatured and disappeared, and the fertilized ovum at the stages from cleavage to blastula stage [is] are transplanted in an uterus to obtain a baby.

Please amend the paragraph beginning at page 8, line 4 as follows:

[At first,] In the first embodiment of the present invention is a carrier for co-

culturing a fertilized ovum of an animal [according to the first aspect of the invention is illustrated].

IN THE CLAIMS

Please amend the claims as follows:

1. (Amended) A carrier for co-culturing with a fertilized ovum of an animal comprising a cell incorporated type three-dimensionally reconstructed tissue for co-culturing the fertilized ovum of an animal [to induce] for the purpose of adhesion and three-dimensional growth of the fertilized ovum.
2. (Amended) The co-culturing carrier according to Claim 1, wherein the cell incorporated type three-dimensionally reconstructed tissue is reconstructed from [any] one or more biological materials which contain at least one cell and are derived from animals selected from the group consisting of cells, tissues [or], and organs [derived from animals and it contains at least one cell(s)].
3. (Amended) The co-culturing carrier according to Claim 1 [or 2, characterized in that], wherein the cell incorporated type three-dimensionally reconstructed tissue [contains an] further comprises one or more extracellular matrix [component (s)] components and/or [a] one or more mesh [network (s), in addition to the incorporated cells] networks.
4. (Amended) The co-culturing carrier according to [any one of Claims 1-3, characterized in that] Claim 1, wherein the cells to be incorporated in the cell incorporated type three-dimensionally reconstructed tissue are cells derived from an animal that is homogeneous or heterogeneous to the fertilized ovum.
5. (Amended) The co-culturing carrier according to [any one of Claims 1-4,

characterized in that] Claim 4, wherein the cells to be incorporated in the cell incorporated type three-dimensionally reconstructed tissue are cells derived from an endometrium.

6. (Amended) The co-culturing carrier according to [any one of Claims 1-5, characterized in that] Claim 1, wherein the cell to be incorporated in the cell incorporated type three-dimensionally reconstructed tissue are pretreated with mitomycin C.

7. (Amended) The co-culturing carrier according to Claim 3, [characterized in that] wherein the extracellular matrix component is gelated.

8. (Amended) The co-culturing carrier according to Claim 3, [characterized in that] wherein the mesh network is composed of [any] one or more natural or synthetic [thread] threads and/or a woven mass thereof.

9. (Amended) The co-culturing carrier according to Claim 3 [or 8, characterized in that], wherein the mesh network is bioabsorptive.

10. (Amended) The method of culturing a fertilized ovum of an animal, [characterized in that] comprising introducing the co-culturing carrier according to [any one of Claims 1-9] Claim 1 [is introduced] into a culture vessel [to culture] and culturing the fertilized ovum of an animal.